APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,507	02/05/2004	Taejoon Kwon	YPL0080US	6812

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EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
01/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>05 November 2009</u>.

2a) ☒ This action is **FINAL**.   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1,2,5-7,10-12 and 15</u> is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-2, 5-7, 10-12, and 15</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a) ☐ All   b) ☐ Some *   c) ☐ None of:

   1. ☐ Certified copies of the priority documents have been received.

   2. ☐ Certified copies of the priority documents have been received in Application No. _____.

   3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
   Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment and Status of the Claims

The amendment filed 11/5/09 has been entered and based upon in the present

Office action.

Claims 3-4, 8-9, and 13-14 are canceled.

Claims 1-2, 5-7, 10-12, and 15 are currently pending and under consideration.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 5-7, 10-12, and 15 are rejected under 35 U.S.C. 101 because the

claimed invention is directed to non-statutory subject matter.

The rejection is reiterated from the previous Office action.

Claims 1-2, 5-7, 10-11, and 15 are drawn to a method and system for

determining a location of a target sequence in a genome sequence, the method

comprising: inputting a target sequence; searching for identifier information and

sequence information corresponding to the target sequence in a crosslink map, wherein

the crosslink map comprises records of sequence information for a plurality of versions

of a genome sequence; determining a reference group comprising a reference sequence

information for an organism, wherein the reference sequence information is represented in the crosslink map by more than a predetermined number of records; calculating a difference value of a start position and an end position of the reference sequence information obtained from the crosslink map; determining a location of the target sequence in the genome sequence by a location shift corresponding to the difference value; and outputting the location of the target sequence in the genome sequence to a user.

The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ; Diehr, 450 U.S. at 192 ; see also Flook, 437 U.S. at 589 n.9 ;Cochrane v. Deener, 94 U.S. 780, 788 (1876). The same test is emphasized by the court in *In re Bilski* as the only test for determining whether a claimed method is a statutory process. Id.

In the instant case, the claimed process is not tied to any particular machine or apparatus. Moreover, there is no physical transformation because the claims are drawn to a process of merely manipulating nucleic acid sequence data without transforming an article or physical subject to a different state or thing. Therefore, at least one embodiment of the claimed method is not a statutory process.

Amendment of the claims to be tied to a particular machine or achieve a physical transformation may overcome the rejection.

However, applicant is reminded that the court has pointed out that the involvement of the particular machine/apparatus or transformation in a claimed process must not merely be insignificant extra-solution activity. See Flook, 437 U.S. at 590. A machine only recited in the data gathering step or an outputting step or preamble would fall into this category of insignificant extra-solution activity.

With regard to claims 1-2, 5-6, and 15, while the systems could be tangible and physical, they may not be a specific particular machine or apparatus. The various "units" and "portions" of the system are not clearly disclosed and claimed as tangible hardware components of the system and may be completely software driven. In Benson, the limitations tying the process to a computer were not actually limiting because the fundamental principle at issue, a particular algorithm, had no utility other than operating on a digital computer. Benson, 409 U.S. at 71-72. Thus, the claim's tie to a digital computer did not reduce the pre-emptive footprint of the claim since all uses of the algorithm were still covered by the claim.

Note that upon reconsideration, the rejection of claim 12, drawn to a computer readable medium is withdrawn as it is interpreted that a computer readable medium having embodied thereon a computer program would not read on a carrier wave, which is a signal.

Applicant's arguments filed 11/5/09 have been fully considered but they are not persuasive. Applicant argues that the claimed are amended to be drawn to a computer system, which based on "webopedia.com" includes not only a computer but the peripheral devices. In response, the examiner does not dispute that the computer system,

per se, includes a computer and its peripheral devices. However, given the use of

"comprising," which is considered an open language, in the claims, the claimed computer

system is a broad genus including embodiments that, while must include the various

unites recited in the claim, could also, but not necessarily, consist of a computer and the

peripheral devices. Therefore, at least one embodiment of the claimed computer system is

drawn to a nonstatutory subject matter.

However, if a computer and/or its peripheral devices are recited in the various

"unit" of the claims, the rejection of the claims drawn to a system would be overcome.

With regard to claims 7, and 10-11, drawn to a method, applicant argues that the

claims are amended to recite that the method is executed by a specifically programmed

computer and thus the claimed process meets the specific machine standard of In re

Bilski. This is not found persuasive because, the "wherein" clause is added in the

preamble and the open language "comprising" is used in the claims. Thus, if only one

step of the method, which is not necessarily one of the recited steps during to the open

language "comprising," is executed on the computer, it meets the requirement that the

method is executed on the computer. In other words, the added "wherein" clause, since

it's in the preamble and due to the word "comprising," does not require that any of the

recited steps are executed on the computer. However, if the claims are amended such that

it's one or more or all of the recited steps are executed on the specifically programmed

computer, the rejection would be overcome.

Applicant is cautioned against introducing new matter into the claims in any

amendment.

The applicant is encouraged to contact the examiner to discuss possible ways of

claim amendment to overcome the rejection in light of the Office's recent "Interim

Examination Instructions for Evaluating Subject Matter Eligibility Under 35 USC 101,"

effective August 24, 2009, which is available at the Office's website at

http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-

25_interim_101_instructions.pdf.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating
     obviousness or nonobviousness.

Claims 1-2, 5-7, 10-12, and 15 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Benson et al. (Nucleic Acids Research, 1999, Vol. 27, pages 38-43;

2002, Vol. 30, pages 17-20) in view of Wheeler et al. (Nucleic Acids Research, 2002,

Vol. 30, pages 13-16).

The claims are drawn to a method and system for determining the location of a target sequence in a genome.

Benson et al. disclose the system of database GenBank and methods of searching the database with a query.

Benson et al. disclose that the GenBank system comprises a plurality of records of different types of sequences including cDNA and genome sequences of different organisms and including different versions of sequences. The database includes different divisions and each division includes different files. For each record, it includes sequences identifiers and accession numbers, scientific name, taxonomy of the source organism, and a table that lists length of the sequence, etc. and features that identifiers coding regions and other sites of biological significance, such as transcription units, intron/exon boundaries, sites of mutations or modifications and other sequence features. See at least page 39, left column. These tables are interpreted as a crosslink map because they link the various sequence features such as intron/exon boundaries and transcriptional units with the locations in the sequences. Benson et al. also disclose various methods of searching the databases including BLAST and PowerBLAST. In the BLAST method, when a query sequence is provided, which is interpreted as being the target sequence recited in the instant claims, the BLAST system searches the entire database of records to find homologous sequences and locations of the query sequence (target sequences) in the sequences including genome sequences in the database, and displays the location of the query/target sequence in the various database record sequences in the form of alignments.

Benson et al. maintains an annual update in the journal of Nucleic Acids Research, and the update in 2002 is provided herein. In the 2002 update, Benson et al.

once again stressed the usefulness of BLAST in the sequence similarity searching and

pointed out that "BLAST is discussed in more detail in a separate article in this issue,"

which is provided herein as a supporting reference.

While Benson et al. do not explicitly recite a system comprising a storage unit, an

information search unit and a location estimation unit, as recited in the instant claims,

given that all the functions performed by these units in the claims are also performed in

Benson et al., it would have been readily apparent and obvious to one having ordinary

skill in the art that the system of BLAST+GenBank would include all these units.

Furthermore, a computer program or algorithm for performing all these functions must

have to be stored in a computer readable medium in the system disclosed by Benson et al.

in order to perform the sequence searching by a computer, etc. as BLAST searches would

have been extremely well known and widely used since its publication in 1990.

Applicant's previous arguments filed 8/13/08 had been fully considered but they

were not found persuasive. Applicant argued that Benson et al. are silent with respect to

at least a crosslink map as in claim 7 that comprises records of sequence information for a

plurality of versions of a genome sequence. This was not found persuasive. As set forth

in the previous Office action and reiterated above, Benson et al. disclose that the

GenBank system comprises a plurality of records of different types of sequences

including cDNA and genome sequences of different organisms including different

versions of sequences. The database includes different divisions and each division

includes different files. For each record, it includes sequences identifiers and accession

numbers, scientific name, taxonomy of the source organism, and a table that lists length

of the sequence, etc. and features that identifiers coding regions and other sites of

biological significance, such as transcription units, intron/exon boundaries, sites of

mutations or modifications and other sequence features. See at least page 39, left column.

These tables are interpreted as a crosslink map because they link the various sequence

features such as intron/exon boundaries and transcriptional units with the locations in the

sequences. Applicant also argued that the table of features taught by Benson et al. is for a

single sequence entry not comprising records of sequence information for a plurality of

versions of a genome sequence. This was deemed unpersuasive because as stated above,

it is all these tables not a particular table that are interpreted to be the crosslink map.

Applicant further argued that Benson et al. do not teach determining a reference group

comprising a reference sequence for an organism, calculating a difference value of a start

position and an end position of the reference sequence or determining a location of the

target sequence in the genome sequence by a location shift. This also was found

unpersuasive because as would have been recognized by one of ordinary skill in the art,

when the BLAST software searches the database for a query sequence, which can be

interpreted as a reference, it compares all the sequences including the start and end

position of the query sequence with all sequences in the database and determines the

location of the query sequence in the sequence(s) identified by the software to be

homologous with, and if the identified sequences are genomic sequences such as human

genome sequences which are in GenBank, it determines the location of the query

sequence in the genome sequences.

    In the arguments later filed 5/12/09, applicant again argued that Benson et al. are

silent with respect to the location estimation unit for determining a reference group

comprising a reference sequence information for an organism having the limitations

recited in claim 1, etc. See page 3 of 5 of the response. This was not found persuasive. As

set forth above, it would have been recognized by one of ordinary skill in the art that

when the BLAST software searches databases such as GenBank, for a query sequence,

which can be interpreted as a reference, it compares all the sequences including the start

and end position of the query sequence with all sequences in the database and determines

the location of the query sequence in the sequence(s) identified by the software to be

homologous with, and if the identified sequences are genomic sequences such as human

genome sequences which are in GenBank, it determines the location of the query

sequence in the genome sequences.

Furthermore, as referenced by Benson et al. (2002), Wheeler et al. disclose

BLAST and many more other search tools such as the OriFinder, etc. With regard to

NCBI BLAST, Wheeler et al. disclose that the BLAST outputs an alignment format

called the "HitTable," which provides a compact, tabular summary of the BLAST search

results including, for each database hit, the positions of alignment starts and stops,

coupled with scores and Expectation Values. Wheeler et al. continue to disclose that in

addition, BLAST can generate a taxonomically organized output that shows the

distribution of BLAST hits by organism in three formats. See at least page 14, left

column. Thus, Benson et al. are not silent with respect to the location estimation unit for

determining a reference group comprising a reference sequence information for an

organism.

Applicant's arguments filed 11/5/09 have also been fully considered and found

unpersuasive. Applicant's arguments appear to be focused on the new limitation added to

the claims: determining a location of the target sequence in the genome sequence ... by

assigning a priority order to the difference value calculated for the reference sequence
information based on number of records for the reference sequence information in the
crosslink map." Applicant argues that the cited references do not teach or suggest at least
this limitation. This is not found persuasive. As pointed out above, Wheeler et al. disclose
that the BLAST outputs an alignment format called the "HitTable," which provides a
compact, tabular summary of the BLAST search results including, for each database hit,
the positions of alignment starts and stops, coupled with scores and Expectation Values,
clearly, the BLAST system does determine the locations of target sequences in relation to
the references including genomic sequences in the GenBank and other databases, and
since scores and expectation values are listed, which show the difference values, these
scores and values are obviously based upon and expectation values themselves show
priority order as would have been apparent to one skilled in the art because expectation
values, which, as Wheeler et al. indicated on page 14, are measure of statistical
significances, show inherently the priority order.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL.

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R.
§1.136 (a). A shortened statutory period for response to this final action is set to
expire three months from the date of this action. In the event a first response is filed
within two months of the mailing date of this final action and the advisory action is
not mailed until after the end of the three-month shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply

expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

Shubo (Joe) Zhou, Ph.D.

Primary Examiner